

MaineCare Services

An Office of the Department of Health and Human Services

John E. Baldacci, Governor

Brenda M. Harvey, Commissioner

Department of Health and Human Services
MaineCare Services
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TTY: 1-800-423-4331

June 23, 2008

Re: Important Advisory on Report on Drug Marketing/Compliance with 22 M.R.S.A. §2698-A

To Whom It May Concern:

This is an advisory regarding a recently provided format by which drug manufacturers and labelers shall report on their marketing expenses in Maine pursuant to Maine law, 22 M.R.S.A. §2698-A and rules promulgated under that statute.

The Maine Department of Health and Human Services advises manufacturers and labelers of the following:

- 1. Categories for reporting may be expanded by the manufacturer or labeler provided that a generalized descriptor is added identifying the nature of the expense. The Department suggests that each added category be labeled "Other" with the description following. This advisory is intended to eliminate the need to avoid mislabeling and should not be used to erode the function of listed categories.
- 2. Values required within a given category may be expanded provided that a descriptor is added. The Department suggests that each added value be labeled "Other" with the description following. This advisory is intended to eliminate the need to avoid mislabeling and should not be used to erode the function of listed values.
- 3. Because of the timing of the issuance of the format and this advisory, the Department will not pursue an enforcement action against a manufacturer or labeler for not filing its report after July 1, 2008, provided that the report is filed by September 1, 2008.
- 4. In the case of a manufacturer or labeler which has compiled information in reliance upon the previously used format, such that to use the new format would make compliance much more burdensome, it may file using the previously used format, provided that it files information also in the new format to the extent that such burden is not generated. In such a case, the



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filing would consist of a complete report in the prior format and a partial report in the new format.

The Department hopes that this approach will transition into an improved reporting format in the future. Questions regarding this advisory may be directed to Jennifer Cook at (207)287-2705 or by email <u>Jennifer.Cook@Maine.gov</u>.

Sincerely,

Brenda McCormick

Director, Division of Healthcare Management and Member Services

Office of MaineCare Services

Maine Department of Health and Human Services

11 SHS, 442 Civic Center Drive

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Cc: Thomas Bradley

Jennifer Cook